



ENZYMATIC THERAPY

What **Better** feels like.™

January 3, 2006

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY®

&
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)
P: 920.469.9099 • F: 920.469.4418 (Phyto)

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Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Stress Essential™* with L-Theanine	Reduce your stress*	L-Theanine (Suntheanine® brand)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-3-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Operations Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Stress Essential™* with L-Theanine	Promotes relaxation and stress reduction.*	L-Theanine (Suntheanine® brand)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Stress Essential™* with L-Theanine	L-theanine is an amino acid naturally found in green tea, which reduces stress, promotes relaxation, eases nervousness due to common every day overwork and fatigue, and reduces nervous irritability.* It can also alleviate nighttime muscle tension and improves sleep.*	L-Theanine (Suntheanine® brand)

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Stress Essential™* with L-Theanine	In a laboratory setting, researchers found that L-theanine is able to cross the blood brain barrier (the protective wall that blocks substances circulating in the blood from reaching the sensitive brain cells) where it can support the activity of certain neurotransmitters in the brain.* ^{2,3} Additional studies have supported this finding, showing that L-theanine causes significant increases of certain neurotransmitter concentrations, such as serotonin and dopamine, which promote muscle relaxation, improve sleep, and support healthy focus and attentiveness.*	L-Theanine (Suntheanine® brand)

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Stress Essential™* with L-Theanine	Scientists have also found that L-theanine is associated with an increase in alpha brain waves, the type of brain wave linked with feelings of relaxation.* In a clinical study, the brain activity of 50 female volunteers was measured before and after supplementation with 50-200 mg of L-theanine. The researchers found that within 30 minutes of administration, a significantly greater amount of alpha brain waves were generated in the L-theanine groups.* This study's results showed the L-theanine supports relaxation by promoting the generation of alpha brain waves.*	L-Theanine (Suntheanine® brand)

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